

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 January 2001 (11.01.2001)

PCT

(10) International Publication Number
WO 01/01887 A1

(51) International Patent Classification⁷: A61F 2/06 (74) Agents: SCOLA, Daniel, A., Jr.; Hoffmann & Baron, LLP, 6900 Jericho Turnpike, Syosset, NY 11791 et al. (US).

(21) International Application Number: PCT/US00/17448

(22) International Filing Date: 23 June 2000 (23.06.2000) (81) Designated States (*national*): CA, JP.

(25) Filing Language: English

(84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

(26) Publication Language: English

(30) Priority Data:
09/347,218 2 July 1999 (02.07.1999) US

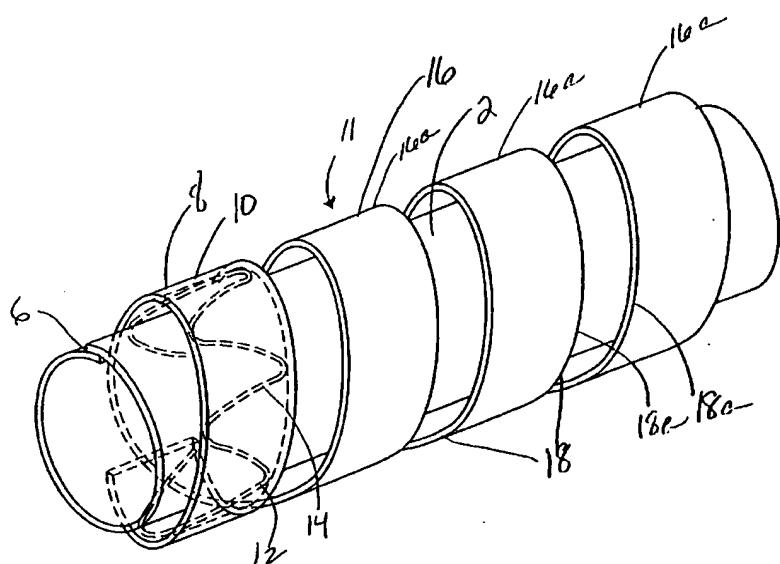
Published:
— *With international search report.*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: IMPROVED COMPOSITE VASCULAR GRAFT



(57) Abstract: A composite stent/graft tubular prosthesis includes an inner PTFE tubular structure, an outer PTFE tubular structure assembled about the inner PTFE tubular structure, and a circumferentially distensible stent interposed between the inner and outer PTFE tubular structures. The outer tubular body is a non-continuous body formed of polytetrafluoroethylene components, providing axial and circumferential compliance to said prosthesis. The outer tubular body completely overlies the distensible stent.

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IMPROVED COMPOSITE VASCULAR GRAFT

FIELD OF THE INVENTION:

The present invention relates generally to a tubular implantable prosthesis formed of porous expanded polytetrafluoroethylene. More particularly, the present invention relates to a composite, multi-layered endoprosthesis having increased axial and radial compliance.

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BACKGROUND OF THE INVENTION:

An intraluminal prosthesis is a medical device commonly known to be used in the treatment of diseased blood vessels. An intraluminal prosthesis is typically used 10 to repair, replace, or otherwise correct a damaged blood vessel. An artery or vein may be diseased in a variety of different ways. The prosthesis may therefore be used to prevent or treat a wide variety of defects such as stenosis of the vessel, thrombosis, occlusion, or an aneurysm.

15

One type of endoluminal prosthesis used in the repair of diseases in various body vessels is a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful to open and support various lumens in the body. For example, stents may be used in the vascular system, urogenital tract and bile duct, as well as in a variety of other applications in the body. Endovascular stents 20 have become widely used for the treatment of stenosis, strictures, and aneurysms in various blood vessels. These devices are implanted within the vessel to open and/or reinforce collapsing or partially occluded sections of the vessel.

Stents are generally open ended and are radially expandable between a 25 generally unexpanded insertion diameter and an expanded implantation diameter which is greater than the unexpanded insertion diameter. Stents are often flexible in configuration, which allows them to be inserted through and conform to tortuous

pathways in the blood vessel. The stent is generally inserted in a radially compressed state and expanded either through a self-expanding mechanism, or through the use of balloon catheters.

5 A graft is another type of commonly known type of intraluminal prosthesis which is used to repair and replace various body vessels. A graft provides an artificial lumen through which blood may flow. Grafts are tubular devices which may be formed of a variety of material, including textiles, and non-textile materials. One type of non-textile material particularly useful as an implantable intraluminal prosthesis is
10 polytetrafluoroethylene (PTFE). PTFE exhibits superior biocompatibility and low thrombogenicity, which makes it particularly useful as vascular graft material in the repair or replacement of blood vessels. In vascular applications, the grafts are manufactured from expanded polytetrafluoroethylene (ePTFE) tubes. These tubes have a microporous structure which allows natural tissue ingrowth and cell
15 endothelization once implanted in the vascular system. This contributes to long term healing and patency of the graft. These tubes may be formed from extruded tubes or may be formed from a sheet of films formed into tubes.

Grafts formed of ePTFE have a fibrous state which is defined by interspaced nodes interconnected by elongated fibrils. The spaces between the node surfaces that is spanned by the fibrils is defined as the internodal distance (IND). Porosity of a graft is measured generally by IND. In order of proper tissue ingrowth and cell endothelization, grafts must have sufficient porosity obtained through expansion.
20 When the term expanded is used to describe PTFE, it is intended to describe PTFE which has been stretched, in accordance with techniques which increase IND and concomitantly porosity. The stretching may be in uni-axially, bi-axially, or multi-axially. The nodes are spaced apart by the stretched fibrils in the direction of the expansion. Properties such as tensile strength, tear strength and radial (hoop) strength are all dependent on the expansion process. Expanding the film by stretching it in two
25 directions that are substantially perpendicular to each other, for example
30

longitudinally and transversely, creates a biaxially oriented material. Films having multi-axially-oriented fibrils may also be made by expanding the film in more than two directions. Porous ePTFE grafts have their greatest strength in directions parallel to the orientation of their fibrils. With the increased strength, however, often comes
5 reduced flexibility.

While ePTFE has been described above as having desirable biocompatibility qualities, tubes comprised of ePTFE, as well as films made into tubes, tend to exhibit axial stiffness, and minimal radial compliance. Longitudinal compliance is of
10 particular importance to intraluminal prosthesis as the device must be delivered through tortuous pathways of a blood vessel to the implantation site where it is expanded. A reduction in axial and radial flexibility makes intraluminal delivery more difficult.

15 Composite intraluminal prosthesis are known in the art. In particular, it is known to combine a stent and a graft to form a composite medical device. Such composite medical devices provide additional support for blood flow through weakened sections of a blood vessel. In endovascular applications the use of a composite graft or a stent/graft combination is becoming increasingly important
20 because the combination not only effectively allows the passage of blood therethrough, but also ensures patency of the implant. But, composite prosthesis, especially those consisting of ePTFE, while exhibiting superior biocompatibility qualities, also exhibit decreased axial and radial compliance. It is therefore desirable to provide an ePTFE composite intraluminal prosthesis which exhibits increased axial
25 and radial compliance.

SUMMARY OF THE INVENTION:

The present invention comprises a composite ePTFE vascular prosthesis. The composite has three layers; an inner tubular ePTFE layer, a discontinuous outer layer,

and a radially deformable stent atop the inner tubular layer and entirely beneath the outer layer.

One advantage of the present invention is that it provides an improved
5 composite ePTFE intraluminal prosthesis exhibiting increased axial and circumferential compliance and flexibility and greater tissue ingrowth.

Another advantage of the present invention is that it provides an improved
stent/graft combination, exhibiting increased axial and circumferential compliance
10 and flexibility.

Another advantage of the present invention is that it provides an improved
composite ePTFE intraluminal prosthesis exhibiting increased axial and circumferential compliance and flexibility and greater tissue ingrowth through the use
15 of multiaxial fibril direction in a non-continuous outer ePTFE tubular body.

It is yet another advantage of the present invention to provide an improved method of forming such composites using preassembled graft/stent strips.

20 The present invention provides a composite intraluminal prosthesis for implantation which may have a substantially continuous ePTFE tubular inner body in combination with a non-continuous outer ePTFE tubular body formed by tubularly assembled polytetrafluoroethylene strips, or components. A circumferentially distensible support structure is interposed between the two PTFE layers. The
25 components or strips comprising the outer tubular body possess a longitudinal length and a width, with said longitudinal length being greater than said widths; the non-continuous, tubular assembled strips providing axial and circumferential compliance to said prosthesis.

A method of forming an intraluminal prosthesis stent/graft with axial and circumferential compliance is provided by combining a non-continuous PTFE tubular outer body over a substantially continuous PTFE tubular inner body, said outer body and inner body supporting a stent thereinbetween. Use of a braided or woven PTFE in at least the outer layer enhances the axial and circumferential compliance, and provides puncture sealing properties to prosthesis of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective showing of a tubular structure which may be used as the inner tubular structure of the prosthesis of the present invention.

Figure 2 is a perspective view of an assembly strip of the present invention, including a planar graft strip and an undulating wire stent, for forming a composite stent/graft prosthesis according to the present invention.

Figure 2A is a perspective showing, partially in section of a portion, of the composite stent/graft prosthesis of the present invention.

Figure 2B is a perspective showing of another stent/graft composite prosthesis of the present invention.

Figure 3 is a perspective view of an assembly strip of the present invention, including a planar graft strip and a substantially linear wire stent, for forming the composite stent graft prosthesis according to the present invention.

Figure 3A is a perspective showing of a portion of a composite stent/graft prosthesis of the present invention.

Figure 4 shows a partial perspective of the stent and exterior surface of the outer PTFE tubular body of another embodiment of the present invention.

Figure 5 shows an enlarged perspective view of the exterior surface of another embodiment of the outer PTFE tubular body.

Figure 6 shows an enlarged perspective view of the exterior surface of another 5 embodiment of the outer PTFE tubular body.

DETAILED DESCRIPTION OF THE INVENTION:

The prosthesis of the preferred embodiment of the present invention is a composite implantable intraluminal prosthesis which is particularly suited for use as a 10 vascular graft. The composite prosthesis of the present invention includes a multi-layer graft structure with radially deformable stent interposed between layers. The present description is meant to describe the preferred embodiments, and is not meant to limit the invention in any way.

15 Shown in Figure 1 is a continuous tubular inner PTFE body 2 which may form one of the layers of the multilayer graft. The braided tubular body is formed by wrapping a PTFE sheet 4 around a mandrel (not shown), to form a tubular body with a seam 6 longitudinally therealong. The seam in the tube may be bonded thermally, adhesively, or with the use of a polymeric solution. It may be fully or partially 20 bonded. Furthermore, the tube may consist of one single layer of the wrap as shown in Figure 1, or it may consist of multiple windings of the PTFE sheet around the longitudinal axial to create a multi-layer inner tube.

25 While in the preferred embodiment, tubular body 2 is formed from a wrapped PTFE sheet, tubes of extruded PTFE may be used to form the continuous inner tubular body of the present invention.

30 Continuous, as used herein, refers to a tubular structure whose surface extends substantially uninterrupted throughout the longitudinal length thereof. In the case of an extruded tube, the tubular structure is completely uninterrupted. In the case of a

sheet formed tube there are no transverse interruptions. As is known in the art, a substantially uninterrupted tubular structure exhibits enhanced strength and sealing properties when used as a vascular graft.

5 Figure 2 depicts an assembly strip 8 for forming a composite stent/graft prosthesis 11 according to the present invention. The assembly strip 8 comprises a planar graft strip 10 and a radially deformable support structure such as planar stent 12 in this embodiment, an undulating wire stent 14. Distensible, as used herein, refers to a stent which may be expanded and contracted radially. The stent 12 may be
10 temporarily fastened to the strip, or simply assembled therewith. The composite prosthesis 11 is made by wrapping the assembly strip about a tubular inner PTFE body 2, and securing the graft strip directly to the tubular graft body. As shown in Figure 2A, preferably the strip is wound helically around the tubular inner body 2. One preferred construction for assembly strip 8 is shown and described in commonly
15 assigned U.S. Patent Application, entitled "Helically Formed Stent/Graft Assembly" and filed at even date herewith. This application is incorporated by reference herein. In an alternate construction depicted in Figure 2B, individual assembly strips, 8', are joined at seams 6' in an annular fashion to form a plurality of spaced apart stent/graft covers over tubular body 2.

20 Various stent types and stent constructions may be employed in the invention. Among the various stents useful include, without limitation, self-expanding stents and balloon expandable extents. The stents may be capable of radially contracting, as well, and in this sense can best be described as radially distensible or deformable.
25 Self-expanding stents include those that have a spring-like action which causes the stent to radially expand, or stents which expand due to the memory properties of the stent material for a particular configuration at a certain temperature. Nitinol is one material which has the ability to perform well while both in spring-like mode, as well as in a memory mode based on temperature. Other materials are of course

contemplated, such as stainless steel, platinum, gold, titanium and other biocompatible metals, as well as polymeric stents.

The configuration of the stent may also be chosen from a host of geometries.

- 5 For example, wire stents can be fastened into a continuous helical pattern, with or without a wave-like or zig-zag in the wire, to form a radially deformable stent. Individual rings or circular members can be linked together such as by struts, sutures, welding or interlacing or locking of the rings to form a tubular stent. Tubular stents useful in the present invention also include those formed by etching or cutting a
10 pattern from a tube. Such stents are often referred to as slotted stents. Furthermore, stents may be formed by etching a pattern into a material or mold and depositing stent material in the pattern, such as by chemical vapor deposition or the like.

In constructing the composite intraluminal prosthesis 11 of Figure 2A, it is not
15 necessary to preassemble strips 8. In one method of construction, the inner tubular body 2 is circumferentially enclosed by stent 12. The stent 12 may be formed from an elongate wire 14 which is helically wound with a plurality of longitudinally spaced turns into an open tubular configuration. The stent may be of the type described in U.S. Patent No. 5,575,816 to Rudnick, et al. Stent 12 is an expandable tubular
20 member which may be either of the balloon-expanded or self-expanded type. Stents of this type are typically introduced intraluminally into the body, and expanded at the implantation site.

The composite endoluminal prosthesis 11 is completed by wrapping strip(s) of
25 ePTFE over the stent, to make a non-continuous outer PTFE tubular body 16 which circumferentially surrounds the inner tube 2 and the stent 12. Non-continuous, as used herein, refers to a tubular structure which is not substantially uninterrupted along its length as it contains at least two spaced apart edges 18 and 18a transverse to the longitudinal surface of the tubular body. The non-continuous outer PTFE tubular

body 16 is comprised of a flat PTFE tape helically wound around the inner tube 2 and stent 12 so as to completely overly the stent.

The outer body 16 possesses edges 18 which define the separate PTFE components, and edges 18a define open spaced in the outer PTFE tubular body 16. The PTFE components shown in outer tube 16 consist of the successively spaced helical turns 16a of an axially wrapped PTFE tape 10. Prior to winding, the PTFE tape 10 has a substantially flat cross-section, and a longitudinal length substantially longer than the width of the tape.

Referring now to Figure 2B, the composite endoluminal prosthesis may be alternatively constructed by winding individual stent sections 12' axially about tube 2, and overlying the stent sections with strips 10', or cutting preassembled strip sections 8' and seaming them at 6'. The embodiment of Figure 2B is also non-continuous defining spaced apart edges 18 identifying open spaces therebetween.

Figure 3 shows an alternate assembly strip construction 19 comprising a planar graft strip 20 assembly with a stent 21, which in this embodiment is a substantially straight wire. In assembling a composite endoluminal prosthesis from assembly strip 19, the strip may be helically wound in a non-overlapping configuration about inner tubular member 2 in a manner similar to that described with respect to Figure 2A. Tape 20 may be secured to inner tubular body 2, sealing the stent within the composite. Alternatively, the stent may be wound about the inner tubular member, and graft strip 20 laid atop the stent. It should also be noted that assembly strip 19 may be cut into segments, each of which may be wound circumferentially about the tube body 2, and seamed in a manner similar to that described with respect to Figure 2B.

Figure 4 depicts a further embodiment of the present invention which also provides a non-continuous outer tube. This embodiment employs an inner tube 2 and

a stent 12 as described above in relation to Figures 2 and 2A. In this preferred embodiment, the composite prosthesis 22 possesses an outer tubular body 24 including a weave, or a braid of individual PTFE tapes. The woven or braided configuration may be two dimensional or may be three dimensional, as shown in 5 Figures 5 and 6.

Figure 5 shows two PTFE tapes combined in a two dimensional matrix, wherein the two tapes comprise the separate components of the non-continuous tubular body 24.

10

Figure 6 shows an enlarged view of a three dimensional braid comprised of three PTFE tapes braided together in three directions. Such braided, knitted or woven construction provides axial and radial compliance to the prosthesis 22 by defining spaces within the braided, knitted or woven extruded structure.

15

In certain applications where enhanced sealing properties are required, a sealant 28, as shown in Figure 6, may be interspersed within the woven or braided matrix to create a non-porous outer tubular body. Sealants which may be used in the prosthesis include FEP, polyurethane, and silicone. Additional sealants include 20 biological materials such as collagen, and hydrogels, polymethylmethacrylate, polyamide, and polycarbonate. Elastomers as sealants will have less impact on flexibility. A suitable sealant provides a substantially sealed outer tube without significantly reducing longitudinal and axial compliance.

25

As shown herein the outer tubular body shown in the above-referenced figures form non-continuous bodies comprised of PTFE components tubularly assembled. The non-continuous structure of the outer tubular body provides the composite prosthesis with enhanced radial and longitudinal, or axial compliance. The radial and axial compliance can, in fact, be varied with the different outer PTFE bodies which 30 may be used, as may be suitable for the use of the intraluminal prosthesis. The non-

continuous outer layer 16 is formed by wrapping one, two, or three or more PTFE tapes in an axial wrap, weave, braid or other non-continuous tubular body consisting of the component PTFE parts defined above.

5 In preferred embodiments the PTFE tape forming the PTFE components is expanded PTFE (ePTFE). The term expanded refers to PTFE which has been stretched uniaxially, biaxially, or multiaxially in a particular direction. The PTFE tape of the prosthesis of the present invention is typically stretched in the longitudinal direction of the tape. When two or more tapes are combined to form the outer tubular body, the resultant tubular body possesses a biaxial, or multiaxial resultant orientation 10 in the aggregate. Because ePTFE exhibits increased strength in the direction of its stretching, the ePTFE tubularly assembled body exhibits the advantage of the increased strength of a biaxial or multiaxial stretched film, but exhibits the advantages of compliance because of its non-continuous surface.

15 The inner PTFE tubular layer may be bonded to the outer PTFE tubular layer through spaces in the open wall of the stent. The bonding may be effectuated with the use of an adhesive, or by adhering the layers together without an adhesive. Bonding of the PTFE layers without an adhesive may take place by such methods as 20 laminating, or sintering of the prosthesis. Furthermore, the stent may be adhered to the inner PTFE tubular layer, the outer PTFE tubular layer, or both. Similarly, such adherence may take place with or without the use of an adhesive.

25 Although illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention.

WHAT IS CLAIMED IS:

1. An implantable composite intraluminal prosthesis comprising:
 - a substantially continuous polytetrafluoroethylene tubular inner body;
 - a longitudinally non-continuous outer tubular body; and
 - a circumferentially distensible support structure interposed between the inner and outer tubular bodies, said outer tubular body being formed of polytetrafluoroethylene components, having a longitudinal length and a width, said longitudinal length being greater than said width, said components completely overlying the dispensable support structure, whereby axial and circumferential compliance is provided to said prosthesis.
- 5 2. A composite intraluminal prosthesis according to claim 1 wherein the outer polytetrafluoroethylene body comprises a polytetrafluoroethylene tape spirally wrapped with a plurality of helical turns in a circumferential direction around the inner tubular body and distensible support structure, wherein each helical turn of said spiral wrap defines one of said polytetrafluoroethylene components.
- 5 3. A composite intraluminal prosthesis according to claim 1 wherein the outer polytetrafluoroethylene body comprises segments of polytetrafluoroethylene tape, each wrapped circumferentially around the inner tubular body and distensible support structure wherein each turn of said segments defines one of said polytetrafluoroethylene components.
4. A composite intraluminal prosthesis according to claim 1 wherein the outer polytetrafluoroethylene body comprises first and second polytetrafluoroethylene tapes interweaved through each other around the inner tubular body, said first and second tapes defining said components.

5. A composite intraluminal prosthesis according to claim 1 wherein the outer tubular body comprises three or more polytetrafluoroethylene tapes arranged in a braided tubular configuration, said three or more tapes defining said components.

6. A composite intraluminal prosthesis according to claim 4 or 5 wherein a sealant is interspersed between said tapes.

7. A composite intraluminal prosthesis according to claim 1 wherein said continuous polytetrafluoroethylene tubular inner body is comprised of a sheet of expanded polytetrafluoroethylene formed into a tubular shape by wrapping said sheet about a longitudinal axis.

8. A method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite comprising:

combining a non-continuous polytetrafluoroethylene tubular outer body over a substantially continuous polytetrafluoroethylene tubular inner body,
5 wherein said outer body and inner body support a distensible support structure therebetween, said outer body completely covering the distensible support structure, said outer body is formed by tubularly-assembled polytetrafluoroethylene components.

9. A method according to claim 8 wherein the non-continuous outer tubular body is formed by spirally wrapping a polytetrafluoroethylene tape with a plurality of helical turns in a circumferential direction around the inner tubular body and distensible support structure to form an outer tubular body, wherein each helical 5 turn of said spiral wrap defines one of said polytetrafluoroethylene components.

10. A method according to claim 8 wherein the non-continuous outer tubular body is formed by circumferentially wrapping segments of a polytetrafluoroethylene tape around the inner tubular body and distensible support

structure to form an outer tubular body wherein each circumferential turn of said segments defines one of said polytetrafluoroethylene components.

11. A method according to claim 8 wherein the outer tubular body is formed by interweaving first and second polytetrafluoroethylene tapes through each other and about the continuous polytetrafluoroethylene inner tubular body and distensible support structure wherein said first and second tapes define said components.

12. A method according to claim 8 wherein the outer tubular body is formed by arranging three or more polytetrafluoroethylene tapes in a braided configuration, wherein said three or more tapes define said components.

13. A method according to claim 11 or 12 wherein a sealant is interspersed between said tapes.

14. A method according to claim 8 wherein the substantially continuous polytetrafluoroethylene tubular inner body is formed by wrapping a sheet of polytetrafluoroethylene around a mandrel into a tubular structure.

15. A method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite, comprising:

combining a polytetrafluoroethylene strip and a distensible support structure to form an assembly strip; and

5 combining said assembly strip with a substantially continuous inner tubular body support by wrapping said assembly strip about said inner tubular body support in a non-overlapping pattern, such that the assembly strip completely covers the distensible support structure forming a non-continuous outer tubular body of polytetrafluoroethylene components.

16. The method of claim 15 wherein segments of said assembly strip are wrapped circumferentially about said inner tubular body support, to form a non-continuous outer tubular body of polytetrafluoroethylene components.

17. The method of claim 15 wherein the polytetrafluoroethylene strip is a tape.

18. The method of claim 17, wherein the assembly strip is wrapped with a plurality of helical turns around the inner tubular body, each helical turn defining one of said polytetrafluoroethylene components.

19. A method of making an implantable intraluminal stent/graft composite prosthesis comprising:

- a) providing a continuous ePTFE tubular inner body;
- b) wrapping a stent about said continuous ePTFE tubular inner body, in a
5 non-overlapping relationship; and
- c) wrapping an ePTFE strip about the tubular inner body and stent, to completely overly the stent.

20. A method of making an implantable intraluminal stent/graft prosthesis, comprising:

- a) providing an ePTFE strip, having a length greater than its width;
- b) providing an unwrapped stent;
- c) assembling the stent with the strip to make an assembly strip with a
5 stent side and an ePTFE strip side;
- d) providing a continuous tubular inner body; and
- e) wrapping the assembly strip around the inner body in non-overlapping relationship, such that the stent is completely covered.

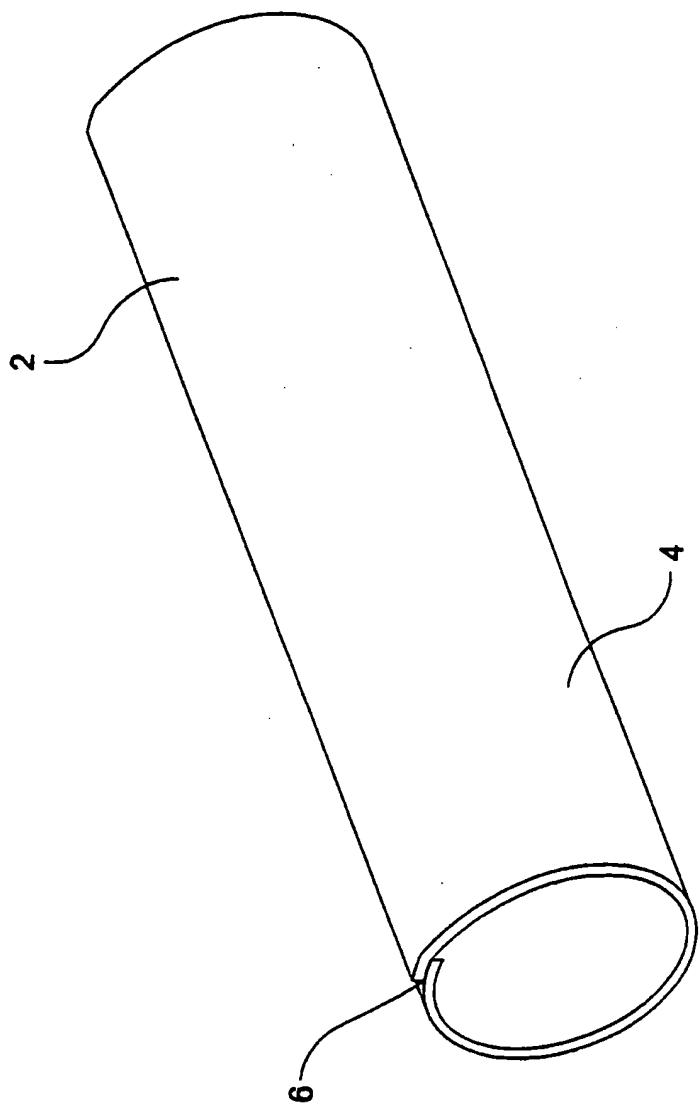
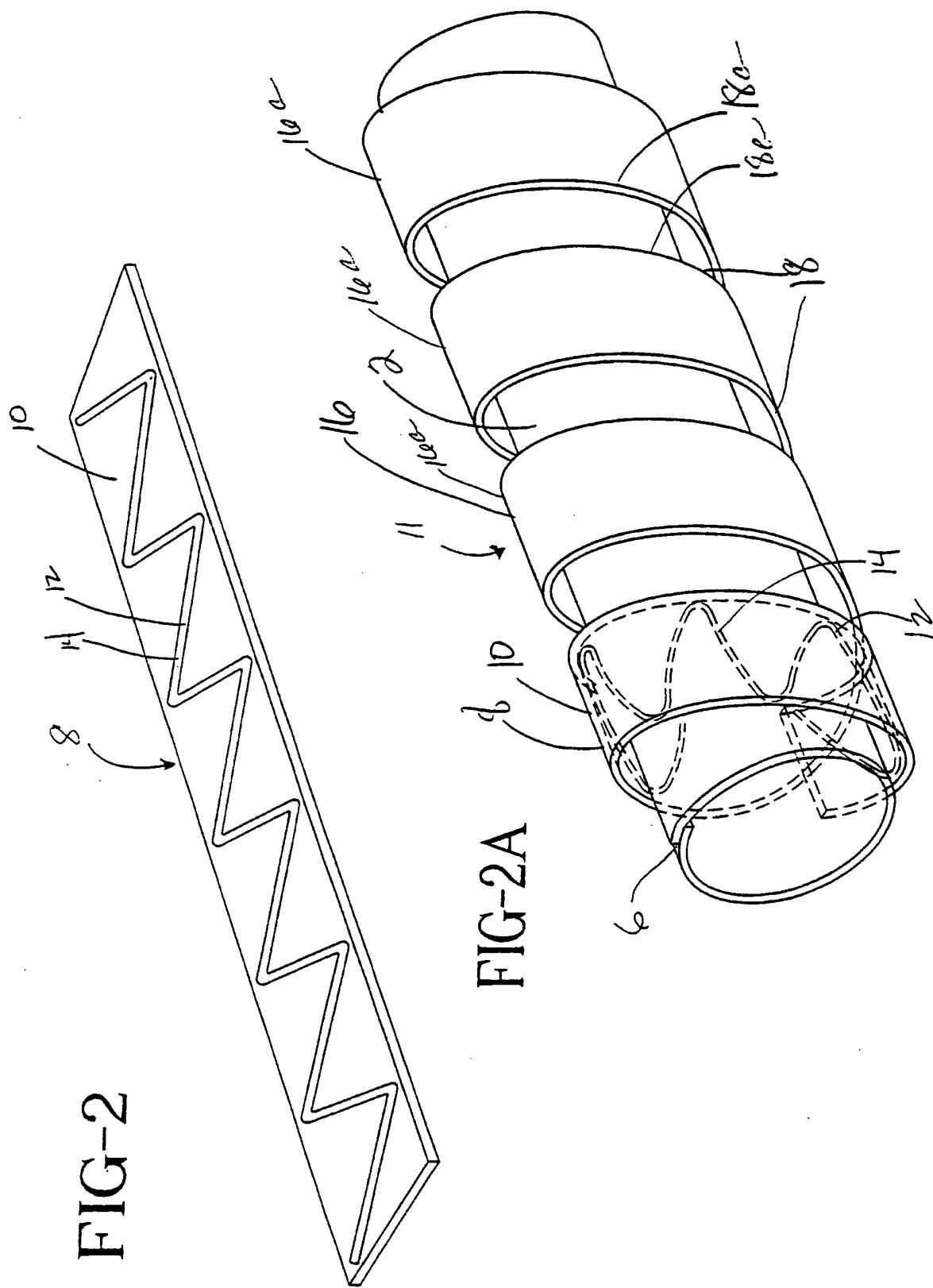


FIG-1

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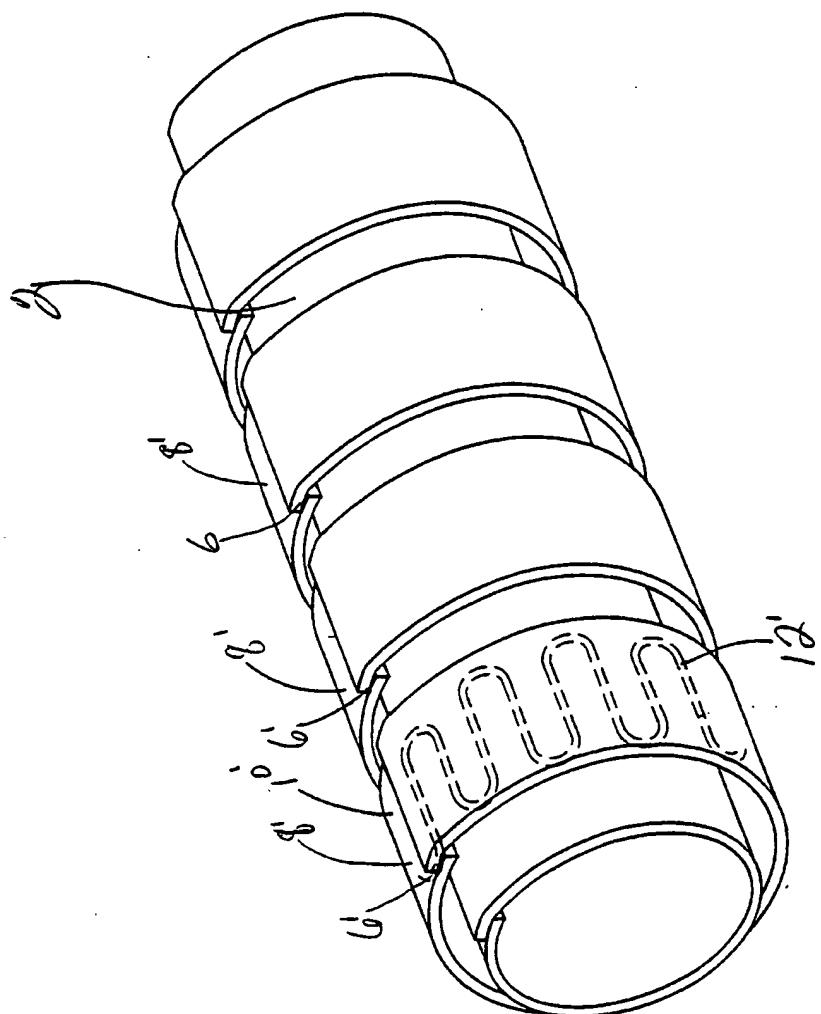
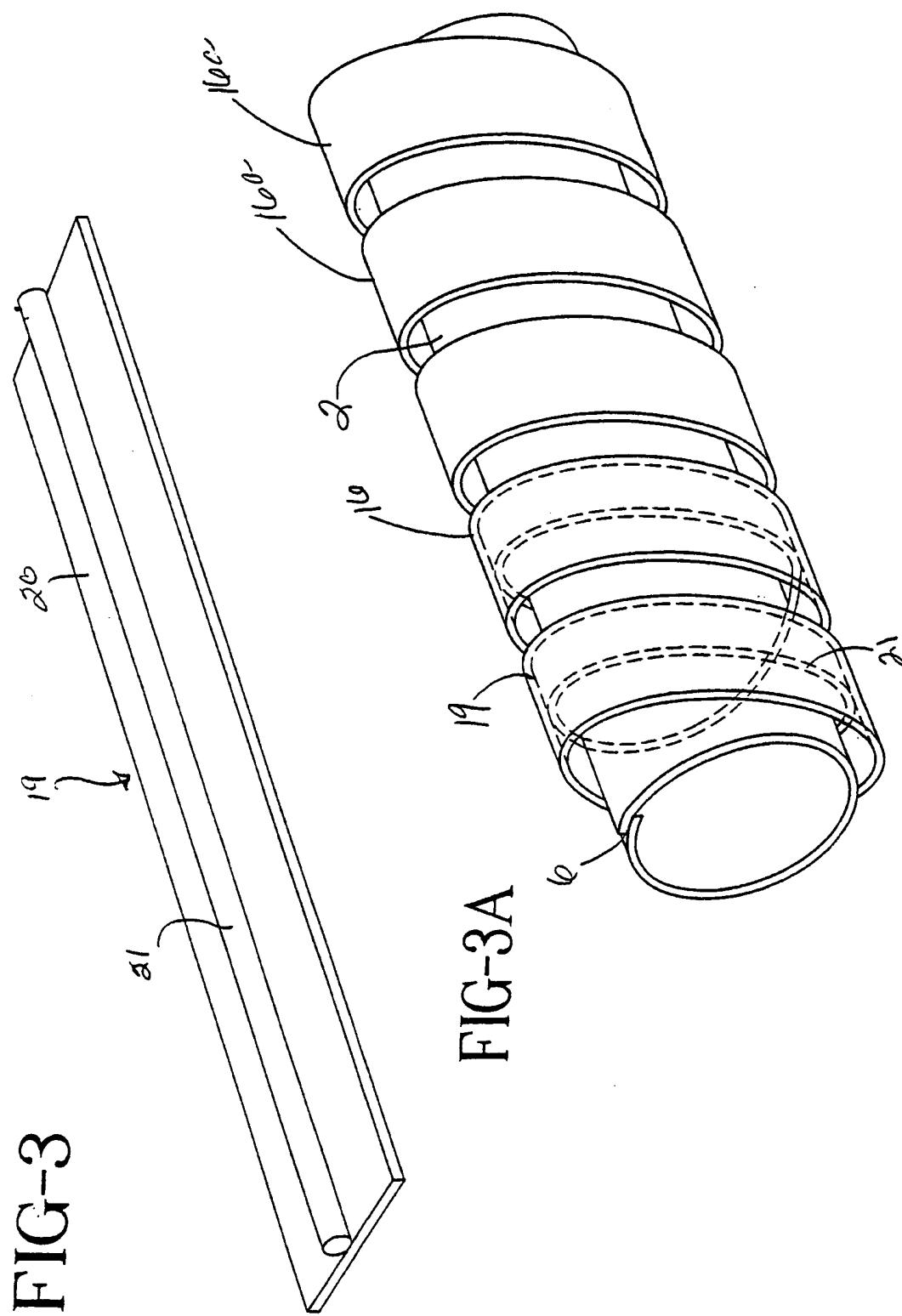


FIG-2B



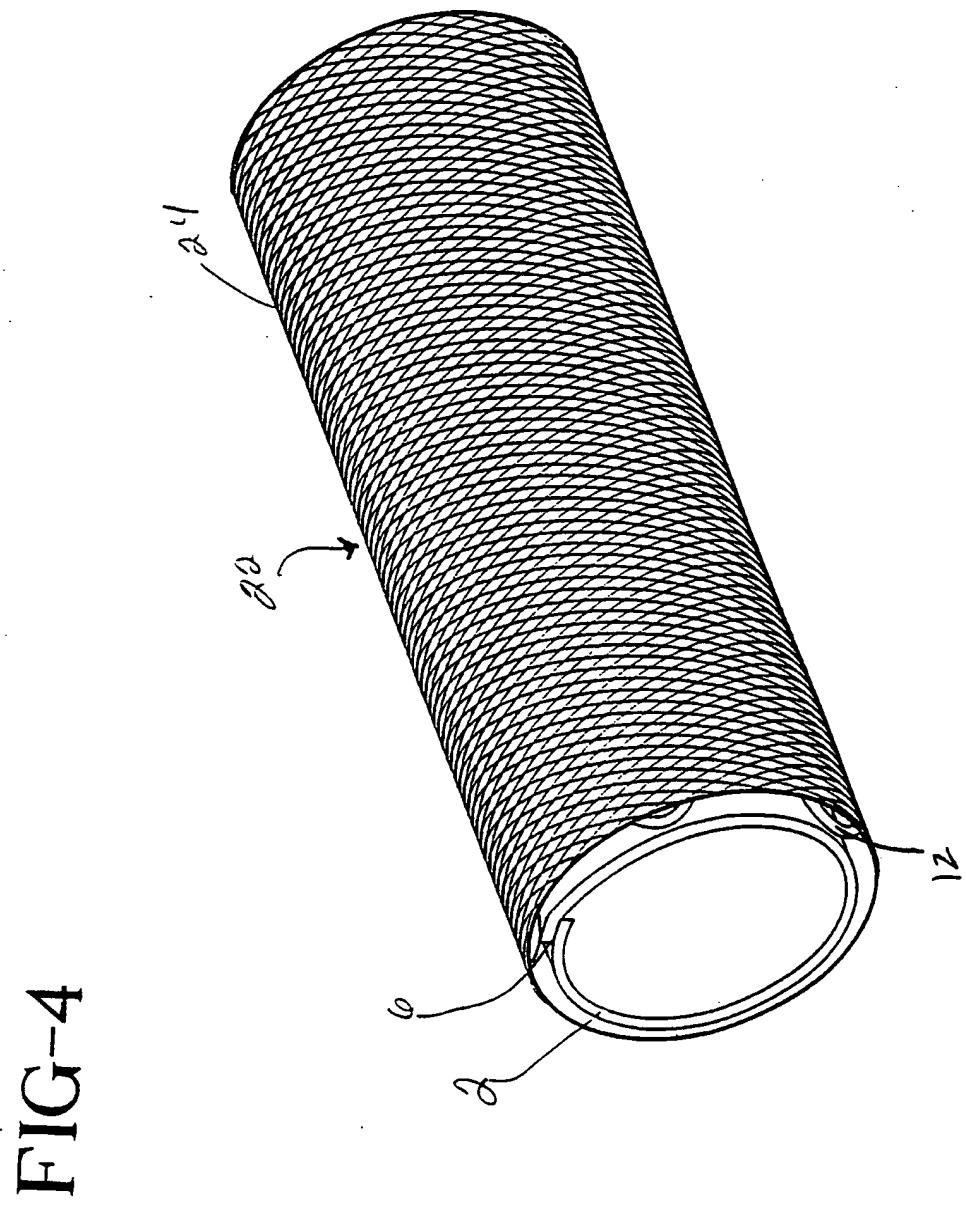


FIG-4

FIG-5

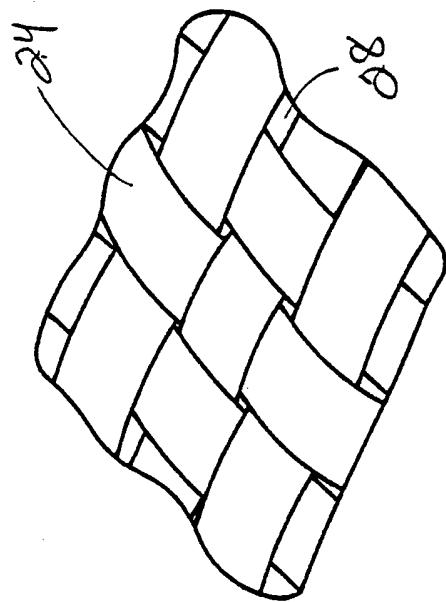
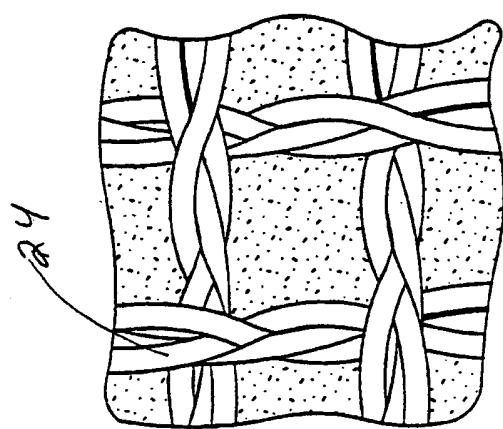


FIG-6



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/17448

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 792 627 A (CARDIOVASCULAR CONCEPTS INC) 3 September 1997 (1997-09-03) column 7, line 22 -column 8, line 11 column 9, line 19 -column 10, line 6 column 10, line 43 -column 11, line 35 ---	1,8,15, 19,20
E	WO 00 45743 A (IMPRA INC) 10 August 2000 (2000-08-10) figures 1-3 claims 1-48 page 4, line 10 - line 14 page 5, line 2 -page 6, line 25 ---	1,3,7,8, 10,14-20

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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INTERNATIONAL SEARCH REPORT

Intern: Application No
PCT/US 00/17448

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 January 2001 (11.01.2001)

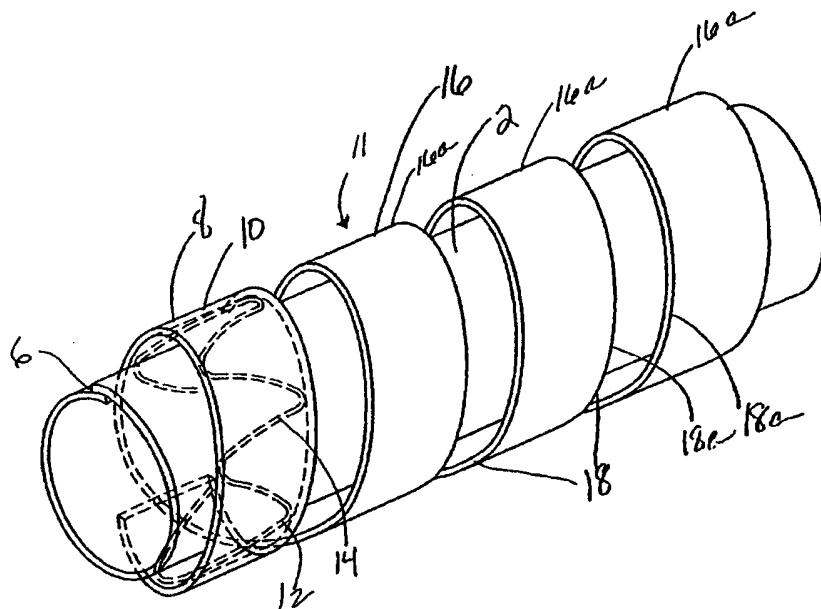
PCT

(10) International Publication Number
WO 01/01887 A1

- (51) International Patent Classification⁷: A61F 2/06 (74) Agents: SCOLA, Daniel, A., Jr.; Hoffmann & Baron, LLP, 6900 Jericho Turnpike, Syosset, NY 11791 et al. (US).
- (21) International Application Number: PCT/US00/17448 (81) Designated States (*national*): CA, JP.
- (22) International Filing Date: 23 June 2000 (23.06.2000) (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (25) Filing Language: English (26) Publication Language: English Published:
— *With international search report.*
- (30) Priority Data:
09/347,218 2 July 1999 (02.07.1999) US (48) Date of publication of this corrected version:
26 April 2001
- (71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US];
One Scimed Place, Maple Grove, MN 55311-1566 (US). (15) Information about Correction:
see PCT Gazette No. 17/2001 of 26 April 2001, Section II
- (72) Inventors: SMITH, Scott; 6950 County Road #10, Chaska, MN 55318 (US). BRODEUR, Christopher; 741 98th Lane N.E., Blaine, MN 55434 (US). For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVED COMPOSITE VASCULAR GRAFT

WO 01/01887 A1



(57) Abstract: A composite stent/graft tubular prosthesis includes an inner PTFE tubular structure, an outer PTFE tubular structure assembled about the inner PTFE tubular structure, and a circumferentially distensible stent interposed between the inner and outer PTFE tubular structures. The outer tubular body is a non-continuous body formed of polytetrafluoroethylene components, providing axial and circumferential compliance to said prosthesis. The outer tubular body completely overlies the distensible stent.

IMPROVED COMPOSITE VASCULAR GRAFT

FIELD OF THE INVENTION:

The present invention relates generally to a tubular implantable prosthesis formed of porous expanded polytetrafluoroethylene. More particularly, the present invention relates to a composite, multi-layered endoprosthesis having increased axial 5 and radial compliance.

BACKGROUND OF THE INVENTION:

An intraluminal prosthesis is a medical device commonly known to be used in the treatment of diseased blood vessels. An intraluminal prosthesis is typically used 10 to repair, replace, or otherwise correct a damaged blood vessel. An artery or vein may be diseased in a variety of different ways. The prosthesis may therefore be used to prevent or treat a wide variety of defects such as stenosis of the vessel, thrombosis, occlusion, or an aneurysm.

15 One type of endoluminal prosthesis used in the repair of diseases in various body vessels is a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful to open and support various lumens in the body. For example, stents may be used in the vascular system, urogenital tract and bile duct, as well as in a variety of other applications in the body. Endovascular stents 20 have become widely used for the treatment of stenosis, strictures, and aneurysms in various blood vessels. These devices are implanted within the vessel to open and/or reinforce collapsing or partially occluded sections of the vessel.

25 Stents are generally open ended and are radially expandable between a generally unexpanded insertion diameter and an expanded implantation diameter which is greater than the unexpanded insertion diameter. Stents are often flexible in configuration, which allows them to be inserted through and conform to tortuous

pathways in the blood vessel. The stent is generally inserted in a radially compressed state and expanded either through a self-expanding mechanism, or through the use of balloon catheters.

5 A graft is another type of commonly known type of intraluminal prosthesis which is used to repair and replace various body vessels. A graft provides an artificial lumen through which blood may flow. Grafts are tubular devices which may be formed of a variety of material, including textiles, and non-textile materials. One type of non-textile material particularly useful as an implantable intraluminal prosthesis is
10 polytetrafluoroethylene (PTFE). PTFE exhibits superior biocompatibility and low thrombogenicity, which makes it particularly useful as vascular graft material in the repair or replacement of blood vessels. In vascular applications, the grafts are manufactured from expanded polytetrafluoroethylene (ePTFE) tubes. These tubes have a microporous structure which allows natural tissue ingrowth and cell
15 endothelialization once implanted in the vascular system. This contributes to long term healing and patency of the graft. These tubes may be formed from extruded tubes or may be formed from a sheet of films formed into tubes.

Grafts formed of ePTFE have a fibrous state which is defined by interspaced
20 nodes interconnected by elongated fibrils. The spaces between the node surfaces that is spanned by the fibrils is defined as the internodal distance (IND). Porosity of a graft is measured generally by IND. In order of proper tissue ingrowth and cell endothelialization, grafts must have sufficient porosity obtained through expansion.
When the term expanded is used to describe PTFE, it is intended to describe PTFE
25 which has been stretched, in accordance with techniques which increase IND and concomitantly porosity. The stretching may be in uni-axially, bi-axially, or multi-axially. The nodes are spaced apart by the stretched fibrils in the direction of the expansion. Properties such as tensile strength, tear strength and radial (hoop) strength are all dependent on the expansion process. Expanding the film by stretching it in two
30 directions that are substantially perpendicular to each other, for example

longitudinally and transversely, creates a biaxially oriented material. Films having multi-axially-oriented fibrils may also be made by expanding the film in more than two directions. Porous ePTFE grafts have their greatest strength in directions parallel to the orientation of their fibrils. With the increased strength, however, often comes
5 reduced flexibility.

While ePTFE has been described above as having desirable biocompatibility qualities, tubes comprised of ePTFE, as well as films made into tubes, tend to exhibit axial stiffness, and minimal radial compliance. Longitudinal compliance is of
10 particular importance to intraluminal prosthesis as the device must be delivered through tortuous pathways of a blood vessel to the implantation site where it is expanded. A reduction in axial and radial flexibility makes intraluminal delivery more difficult.

15 Composite intraluminal prostheses are known in the art. In particular, it is known to combine a stent and a graft to form a composite medical device. Such composite medical devices provide additional support for blood flow through weakened sections of a blood vessel. In endovascular applications the use of a composite graft or a stent/graft combination is becoming increasingly important
20 because the combination not only effectively allows the passage of blood therethrough, but also ensures patency of the implant. But, composite prostheses, especially those consisting of ePTFE, while exhibiting superior biocompatibility qualities, also exhibit decreased axial and radial compliance. It is therefore desirable to provide an ePTFE composite intraluminal prosthesis which exhibits increased axial
25 and radial compliance.

SUMMARY OF THE INVENTION:

The present invention comprises a composite ePTFE vascular prosthesis. The composite has three layers; an inner tubular ePTFE layer, a discontinuous outer layer,

and a radially deformable stent atop the inner tubular layer and entirely beneath the outer layer.

One advantage of the present invention is that it provides an improved
5 composite ePTFE intraluminal prosthesis exhibiting increased axial and circumferential compliance and flexibility and greater tissue ingrowth.

Another advantage of the present invention is that it provides an improved
stent/graft combination, exhibiting increased axial and circumferential compliance
10 and flexibility.

Another advantage of the present invention is that it provides an improved composite ePTFE intraluminal prosthesis exhibiting increased axial and circumferential compliance and flexibility and greater tissue ingrowth through the use
15 of multiaxial fibril direction in a non-continuous outer ePTFE tubular body.

It is yet another advantage of the present invention to provide an improved method of forming such composites using preassembled graft/stent strips.

20 The present invention provides a composite intraluminal prosthesis for implantation which may have a substantially continuous ePTFE tubular inner body in combination with a non-continuous outer ePTFE tubular body formed by tubularly assembled polytetrafluoroethylene strips, or components. A circumferentially distensible support structure is interposed between the two PTFE layers. The
25 components or strips comprising the outer tubular body possess a longitudinal length and a width, with said longitudinal length being greater than said widths; the non-continuous, tubular assembled strips providing axial and circumferential compliance to said prosthesis.

A method of forming an intraluminal prosthesis stent/graft with axial and circumferential compliance is provided by combining a non-continuous PTFE tubular outer body over a substantially continuous PTFE tubular inner body, said outer body and inner body supporting a stent thereinbetween. Use of a braided or woven PTFE in at least the outer layer enhances the axial and circumferential compliance, and provides puncture sealing properties to prosthesis of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective showing of a tubular structure which may be used as the inner tubular structure of the prosthesis of the present invention.

Figure 2 is a perspective view of an assembly strip of the present invention, including a planar graft strip and an undulating wire stent, for forming a composite stent/graf t prosthesis according to the present invention.

Figure 2A is a perspective showing, partially in section of a portion, of the composite stent/graf t prosthesis of the present invention.

Figure 2B is a perspective showing of another stent/graf t composite prosthesis of the present invention.

Figure 3 is a perspective view of an assembly strip of the present invention, including a planar graft strip and a substantially linear wire stent, for forming the composite stent graft prosthesis according to the present invention.

Figure 3A is a perspective showing of a portion of a composite stent/graf t prosthesis of the present invention.

Figure 4 shows a partial perspective of the stent and exterior surface of the outer PTFE tubular body of another embodiment of the present invention.

Figure 5 shows an enlarged perspective view of the exterior surface of another embodiment of the outer PTFE tubular body.

5 Figure 6 shows an enlarged perspective of the exterior surface of another embodiment of the outer PTFE tubular body.

DETAILED DESCRIPTION OF THE INVENTION:

10 The prosthesis of the preferred embodiment of the present invention is a composite implantable intraluminal prosthesis which is particularly suited for use as a vascular graft. The composite prosthesis of the present invention includes a multi-layer graft structure with radially deformable stent interposed between layers. The present description is meant to describe the preferred embodiments, and is not meant to limit the invention in any way.

15 Shown in Figure 1 is a continuous tubular inner PTFE body 2 which may form one of the layers of the multilayer graft. The braided tubular body is formed by wrapping a PTFE sheet 4 around a mandrel (not shown), to form a tubular body with a seam 6 longitudinally therealong. The seam in the tube may be bonded thermally, adhesively, or with the use of a polymeric solution. It may be fully or partially
20 bonded. Furthermore, the tube may consist of one single layer of the wrap as shown in Figure 1, or it may consist of multiple windings of the PTFE sheet around the longitudinal axial to create a multi-layer inner tube.

25 While in the preferred embodiment, tubular body 2 is formed from a wrapped PTFE sheet, tubes of extruded PTFE may be used to form the continuous inner tubular body of the present invention.

30 Continuous, as used herein, refers to a tubular structure whose surface extends substantially uninterrupted throughout the longitudinal length thereof. In the case of an extruded tube, the tubular structure is completely uninterrupted. In the case of a

sheet formed tube there are no transverse interruptions. As is known in the art, a substantially uninterrupted tubular structure exhibits enhanced strength and sealing properties when used as a vascular graft.

5 Figure 2 depicts an assembly strip 8 for forming a composite stent/graft prosthesis 11 according to the present invention. The assembly strip 8 comprises a planar graft strip 10 and a radially deformable support structure such as planar stent 12 in this embodiment, an undulating wire stent 14. Distensible, as used herein, refers to a stent which may be expanded and contracted radially. The stent 12 may be
10 temporarily fastened to the strip, or simply assembled therewith. The composite prosthesis 11 is made by wrapping the assembly strip about a tubular inner PTFE body 2, and securing the graft strip directly to the tubular graft body. As shown in Figure 2A, preferably the strip is wound helically around the tubular inner body 2. One preferred construction for assembly strip 8 is shown and described in commonly
15 assigned U.S. Patent Application, entitled "Helically Formed Stent/Graft Assembly" and filed at even date herewith. This application is incorporated by reference herein. In an alternate construction depicted in Figure 2B, individual assembly strips, 8', are joined at seams 6' in an annular fashion to form a plurality of spaced apart stent/graf covers over tubular body 2.

20

Various stent types and stent constructions may be employed in the invention. Among the various stents useful include, without limitation, self-expanding stents and balloon expandable extents. The stents may be capable of radially contracting, as well, and in this sense can best be described as radially distensible or deformable.
25 Self-expanding stents include those that have a spring-like action which causes the stent to radially expand, or stents which expand due to the memory properties of the stent material for a particular configuration at a certain temperature. Nitinol is one material which has the ability to perform well while both in spring-like mode, as well as in a memory mode based on temperature. Other materials are of course

contemplated, such as stainless steel, platinum, gold, titanium and other biocompatible metals, as well as polymeric stents.

The configuration of the stent may also be chosen from a host of geometries.

- 5 For example, wire stents can be fastened into a continuous helical pattern, with or without a wave-like or zig-zag in the wire, to form a radially deformable stent. Individual rings or circular members can be linked together such as by struts, sutures, welding or interlacing or locking of the rings to form a tubular stent. Tubular stents useful in the present invention also include those formed by etching or cutting a
10 pattern from a tube. Such stents are often referred to as slotted stents. Furthermore, stents may be formed by etching a pattern into a material or mold and depositing stent material in the pattern, such as by chemical vapor deposition or the like.

In constructing the composite intraluminal prosthesis 11 of Figure 2A, it is not
15 necessary to preassemble strips 8. In one method of construction, the inner tubular body 2 is circumferentially enclosed by stent 12. The stent 12 may be formed from an elongate wire 14 which is helically wound with a plurality of longitudinally spaced turns into an open tubular configuration. The stent may be of the type described in U.S. Patent No. 5,575,816 to Rudnick, et al. Stent 12 is an expandable tubular
20 member which may be either of the balloon-expanded or self-expanded type. Stents of this type are typically introduced intraluminally into the body, and expanded at the implantation site.

The composite endoluminal prosthesis 11 is completed by wrapping strip(s) of
25 ePTFE over the stent, to make a non-continuous outer PTFE tubular body 16 which circumferentially surrounds the inner tube 2 and the stent 12. Non-continuous, as used herein, refers to a tubular structure which is not substantially uninterrupted along its length as it contains at least two spaced apart edges 18 and 18a transverse to the longitudinal surface of the tubular body. The non-continuous outer PTFE tubular

body 16 is comprised of a flat PTFE tape helically wound around the inner tube 2 and stent 12 so as to completely overly the stent.

The outer body 16 possesses edges 18 which define the separate PTFE
5 components, and edges 18a define open spaced in the outer PTFE tubular body 16. The PTFE components shown in outer tube 16 consist of the successively spaced helical turns 16a of an axially wrapped PTFE tape 10. Prior to winding, the PTFE tape 10 has a substantially flat cross-section, and a longitudinal length substantially longer than the width of the tape.

10 Referring now to Figure 2B, the composite endoluminal prosthesis may be alternatively constructed by winding individual stent sections 12' axially about tube 2, and overlying the stent sections with strips 10', or cutting preassembled strip sections 8' and seaming them at 6'. The embodiment of Figure 2B is also non-continuous
15 defining spaced apart edges 18 identifying open spaces therebetween.

Figure 3 shows an alternate assembly strip construction 19 comprising a planar graft strip 20 assembly with a stent 21, which in this embodiment is a substantially straight wire. In assembling a composite endoluminal prosthesis from assembly strip
20, the strip may be helically wound in a non-overlapping configuration about inner tubular member 2 in a manner similar to that described with respect to Figure 2A. Tape 20 may be secured to inner tubular body 2, sealing the stent within the composite. Alternatively, the stent may be wound about the inner tubular member, and graft strip 20 laid atop the stent. It should also be noted that assembly strip 19
25 may be cut into segments, each of which may be wound circumferentially about the tube body 2, and seamed in a manner similar to that described with respect to Figure 2B.

Figure 4 depicts a further embodiment of the present invention which also
30 provides a non-continuous outer tube. This embodiment employs an inner tube 2 and

a stent 12 as described above in relation to Figures 2 and 2A. In this preferred embodiment, the composite prosthesis 22 possesses an outer tubular body 24 including a weave, or a braid of individual PTFE tapes. The woven or braided configuration may be two dimensional or may be three dimensional, as shown in
5 Figures 5 and 6.

Figure 5 shows two PTFE tapes combined in a two dimensional matrix, wherein the two tapes comprise the separate components of the non-continuous tubular body 24.

10

Figure 6 shows an enlarged view of a three dimensional braid comprised of three PTFE tapes braided together in three directions. Such braided, knitted or woven construction provides axial and radial compliance to the prosthesis 22 by defining spaces within the braided, knitted or woven extruded structure.

15

In certain applications where enhanced sealing properties are required, a sealant 28, as shown in Figure 6, may be interspersed within the woven or braided matrix to create a non-porous outer tubular body. Sealants which may be used in the prosthesis include FEP, polyurethane, and silicone. Additional sealants include
20 biological materials such as collagen, and hydrogels, polymethylmethacrylate, polyamide, and polycarbonate. Elastomers as sealants will have less impact on flexibility. A suitable sealant provides a substantially sealed outer tube without significantly reducing longitudinal and axial compliance.

25

As shown herein the outer tubular body shown in the above-referenced figures form non-continuous bodies comprised of PTFE components tubularly assembled. The non-continuous structure of the outer tubular body provides the composite prosthesis with enhanced radial and longitudinal, or axial compliance. The radial and axial compliance can, in fact, be varied with the different outer PTFE bodies which
30 may be used, as may be suitable for the use of the intraluminal prosthesis. The non-

continuous outer layer 16 is formed by wrapping one, two, or three or more PTFE tapes in an axial wrap, weave, braid or other non-continuous tubular body consisting of the component PTFE parts defined above.

5 In preferred embodiments the PTFE tape forming the PTFE components is expanded PTFE (ePTFE). The term expanded refers to PTFE which has been stretched uniaxially, biaxially, or multiaxially in a particular direction. The PTFE tape of the prosthesis of the present invention is typically stretched in the longitudinal direction of the tape. When two or more tapes are combined to form the outer tubular body, the resultant tubular body possesses a biaxial, or multiaxial resultant orientation 10 in the aggregate. Because ePTFE exhibits increased strength in the direction of its stretching, the ePTFE tubularly assembled body exhibits the advantage of the increased strength of a biaxial or multiaxial stretched film, but exhibits the advantages of compliance because of its non-continuous surface.

15 The inner PTFE tubular layer may be bonded to the outer PTFE tubular layer through spaces in the open wall of the stent. The bonding may be effectuated with the use of an adhesive, or by adhering the layers together without an adhesive. Bonding of the PTFE layers without an adhesive may take place by such methods as 20 laminating, or sintering of the prosthesis. Furthermore, the stent may be adhered to the inner PTFE tubular layer, the outer PTFE tubular layer, or both. Similarly, such adherence may take place with or without the use of an adhesive.

25 Although illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention.

WHAT IS CLAIMED IS:

1. An implantable composite intraluminal prosthesis comprising:
 - a substantially continuous polytetrafluoroethylene tubular inner body;
 - a longitudinally non-continuous outer tubular body; and
 - a circumferentially distensible support structure interposed between the inner and outer tubular bodies, said outer tubular body being formed of polytetrafluoroethylene components, having a longitudinal length and a width, said longitudinal length being greater than said width, said components completely overlying the dispensable support structure, whereby axial and circumferential compliance is provided to said prosthesis.
- 5 2. A composite intraluminal prosthesis according to claim 1 wherein the outer polytetrafluoroethylene body comprises a polytetrafluoroethylene tape spirally wrapped with a plurality of helical turns in a circumferential direction around the inner tubular body and distensible support structure, wherein each helical turn of said spiral wrap defines one of said polytetrafluoroethylene components.
- 5 3. A composite intraluminal prosthesis according to claim 1 wherein the outer polytetrafluoroethylene body comprises segments of polytetrafluoroethylene tape, each wrapped circumferentially around the inner tubular body and distensible support structure wherein each turn of said segments defines one of said polytetrafluoroethylene components.
4. A composite intraluminal prosthesis according to claim 1 wherein the outer polytetrafluoroethylene body comprises first and second polytetrafluoroethylene tapes interweaved through each other around the inner tubular body, said first and second tapes defining said components.

5. A composite intraluminal prosthesis according to claim 1 wherein the outer tubular body comprises three or more polytetrafluoroethylene tapes arranged in a braided tubular configuration, said three or more tapes defining said components.

6. A composite intraluminal prosthesis according to claim 4 or 5 wherein a sealant is interspersed between said tapes.

7. A composite intraluminal prosthesis according to claim 1 wherein said continuous polytetrafluoroethylene tubular inner body is comprised of a sheet of expanded polytetrafluoroethylene formed into a tubular shape by wrapping said sheet about a longitudinal axis.

8. A method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite comprising:

combining a non-continuous polytetrafluoroethylene tubular outer body over a substantially continuous polytetrafluoroethylene tubular inner body,
5 wherein said outer body and inner body support a distensible support structure therebetween, said outer body completely covering the distensible support structure, said outer body is formed by tubularly-assembled polytetrafluoroethylene components.

9. A method according to claim 8 wherein the non-continuous outer tubular body is formed by spirally wrapping a polytetrafluoroethylene tape with a plurality of helical turns in a circumferential direction around the inner tubular body and distensible support structure to form an outer tubular body, wherein each helical
5 turn of said spiral wrap defines one of said polytetrafluoroethylene components.

10. A method according to claim 8 wherein the non-continuous outer tubular body is formed by circumferentially wrapping segments of a polytetrafluoroethylene tape around the inner tubular body and distensible support

structure to form an outer tubular body wherein each circumferential turn of said segments defines one of said polytetrafluoroethylene components.

11. A method according to claim 8 wherein the outer tubular body is formed by interweaving first and second polytetrafluoroethylene tapes through each other and about the continuous polytetrafluoroethylene inner tubular body and distensible support structure wherein said first and second tapes define said components.

12. A method according to claim 8 wherein the outer tubular body is formed by arranging three or more polytetrafluoroethylene tapes in a braided configuration, wherein said three or more tapes define said components.

13. A method according to claim 11 or 12 wherein a sealant is interspersed between said tapes.

14. A method according to claim 8 wherein the substantially continuous polytetrafluoroethylene tubular inner body is formed by wrapping a sheet of polytetrafluoroethylene around a mandrel into a tubular structure.

15. A method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite, comprising:

combining a polytetrafluoroethylene strip and a distensible support structure to form an assembly strip; and

5 combining said assembly strip with a substantially continuous inner tubular body support by wrapping said assembly strip about said inner tubular body support in a non-overlapping pattern, such that the assembly strip completely covers the distensible support structure forming a non-continuous outer tubular body of polytetrafluoroethylene components.

16. The method of claim 15 wherein segments of said assembly strip are wrapped circumferentially about said inner tubular body support, to form a non-continuous outer tubular body of polytetrafluoroethylene components.

17. The method of claim 15 wherein the polytetrafluoroethylene strip is a tape.

18. The method of claim 17, wherein the assembly strip is wrapped with a plurality of helical turns around the inner tubular body, each helical turn defining one of said polytetrafluoroethylene components.

19. A method of making an implantable intraluminal stent/graft composite prosthesis comprising:

- a) providing a continuous ePTFE tubular inner body;
- b) wrapping a stent about said continuous ePTFE tubular inner body, in a
5 non-overlapping relationship; and
- c) wrapping an ePTFE strip about the tubular inner body and stent, to completely overly the stent.

20. A method of making an implantable intraluminal stent/graft prosthesis, comprising:

- a) providing an ePTFE strip, having a length greater than its width;
- b) providing an unwrapped stent;
- c) assembling the stent with the strip to make an assembly strip with a
5 stent side and an ePTFE strip side;
- d) providing a continuous tubular inner body; and
- e) wrapping the assembly strip around the inner body in non-overlapping relationship, such that the stent is completely covered.

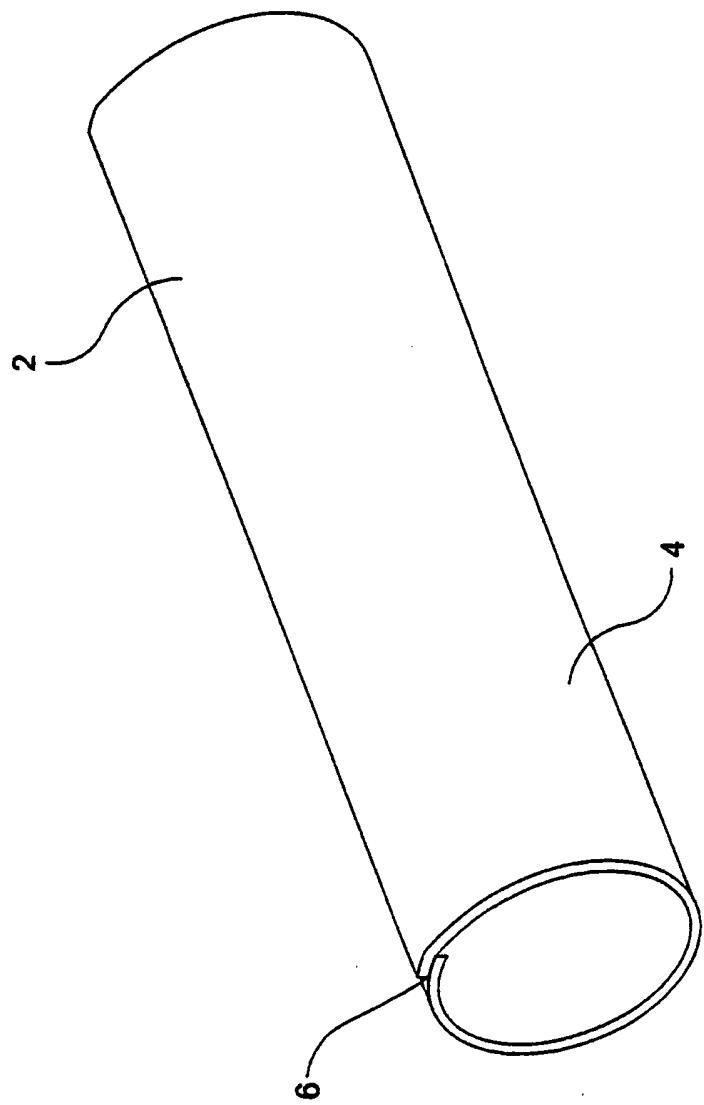


FIG-1

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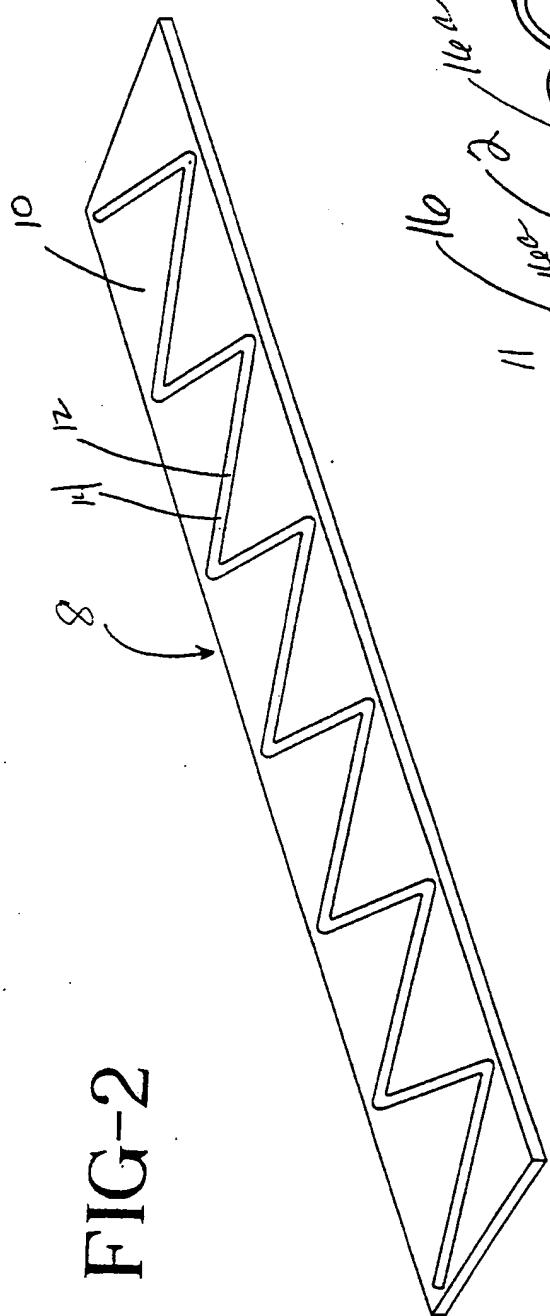
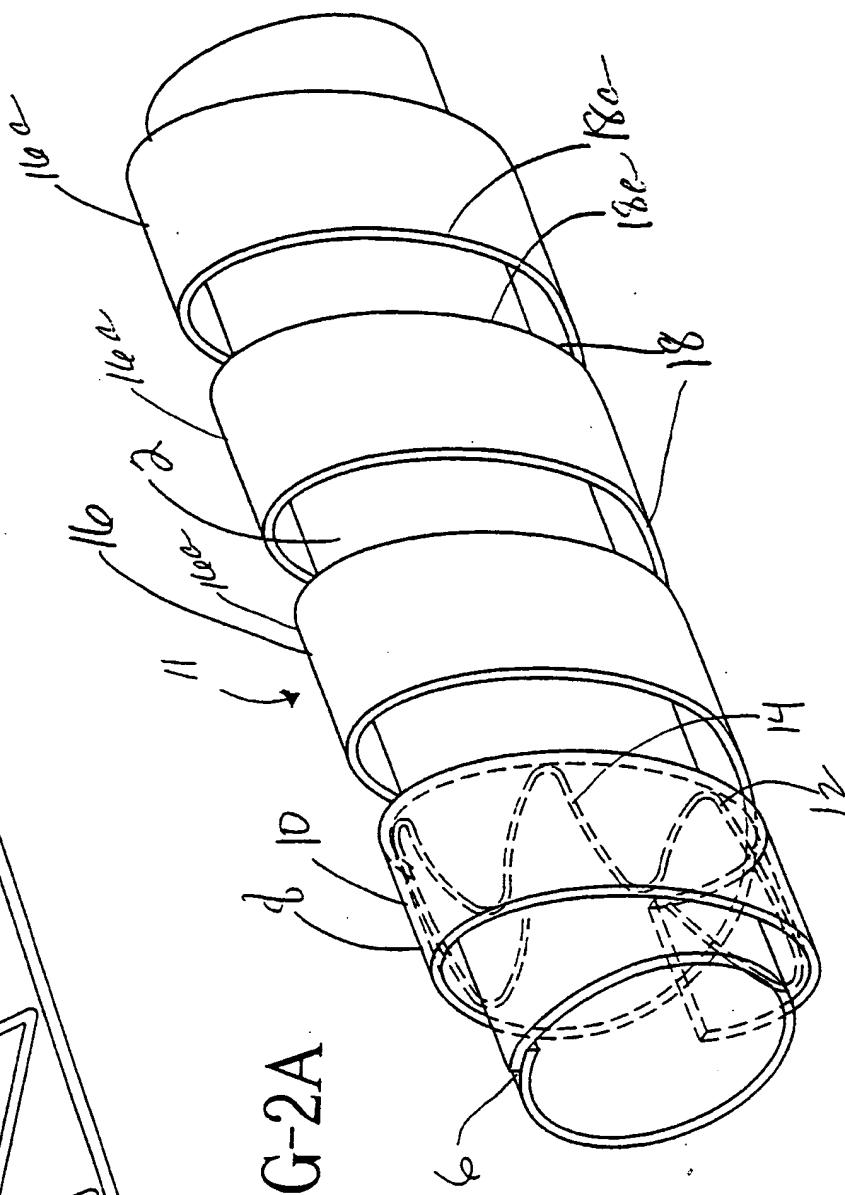


FIG-2A



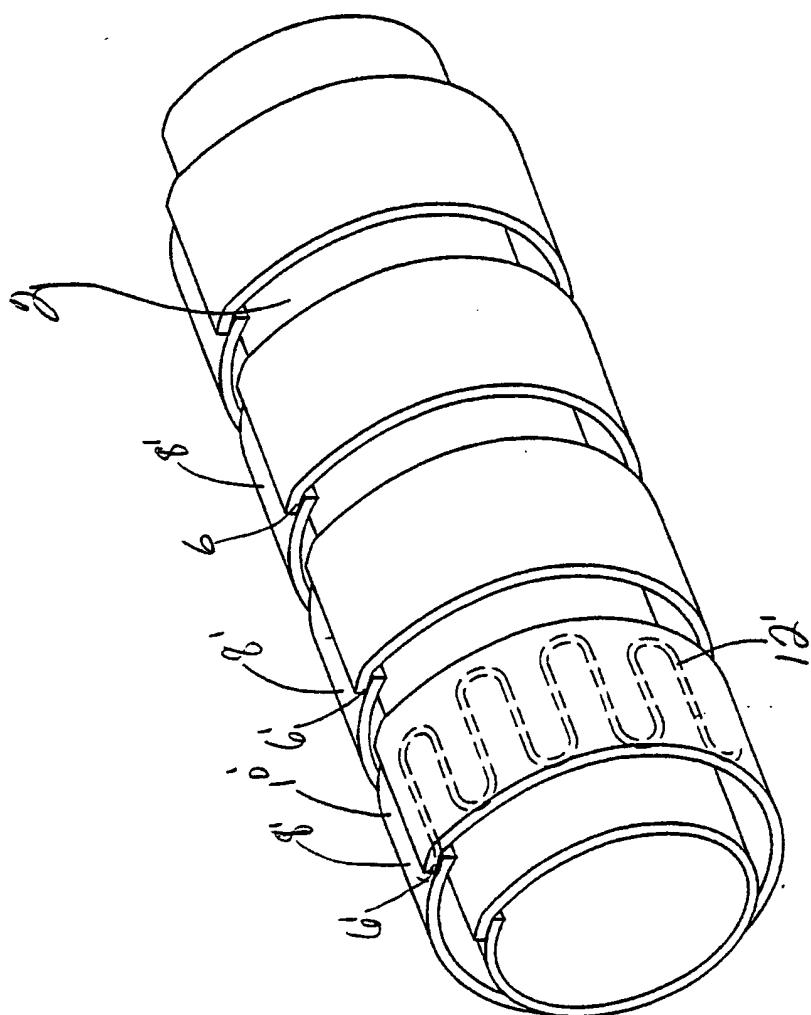
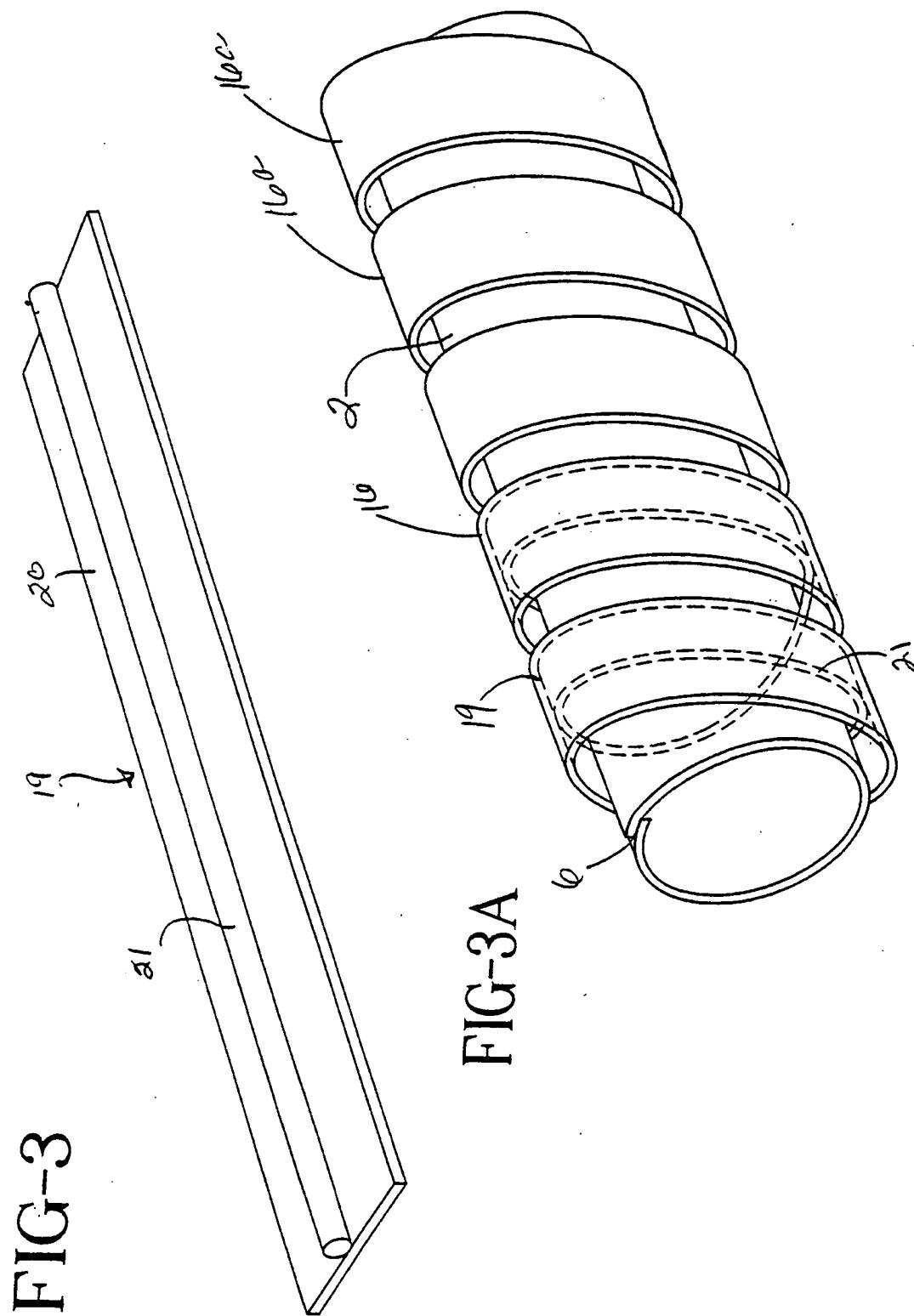


FIG-2B



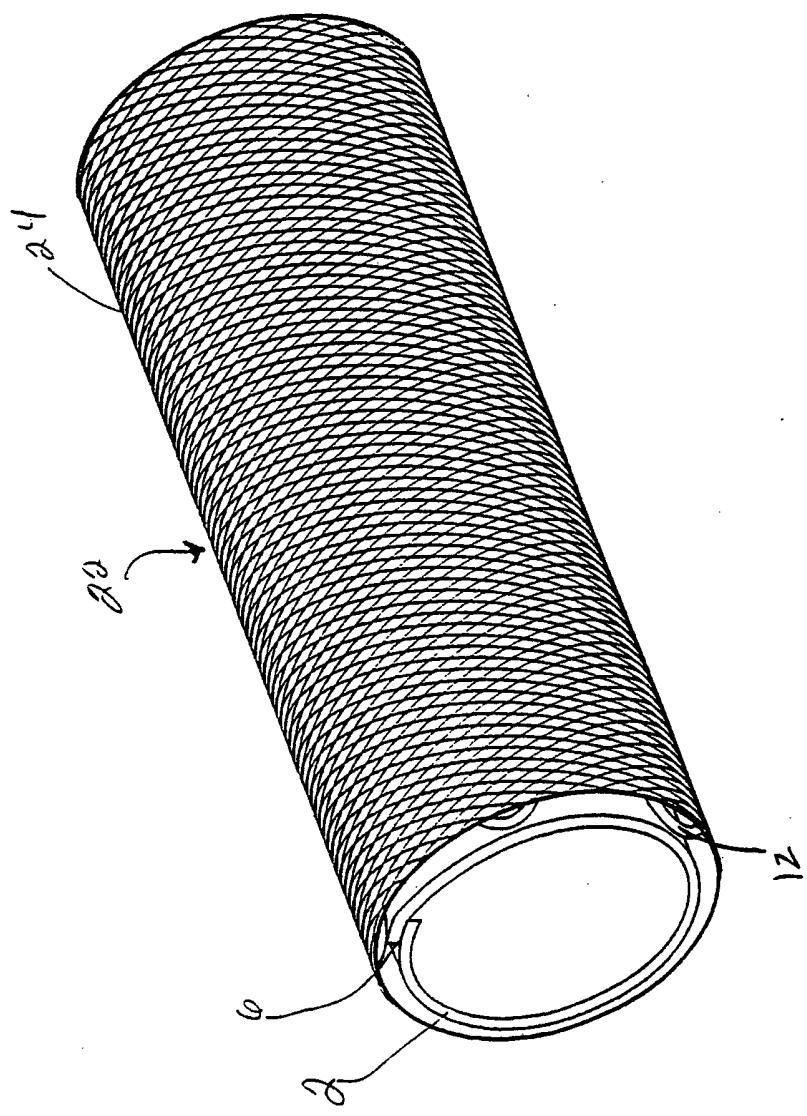


FIG-4

FIG-6

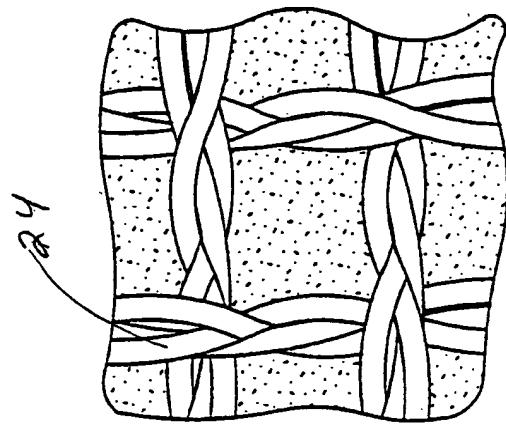
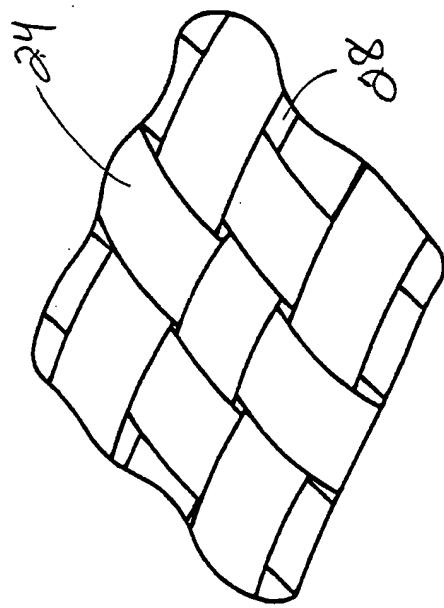


FIG-5



INTERNATIONAL SEARCH REPORT

Intern'l Application No

PCT/US 00/17448

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>EP 0 792 627 A (CARDIOVASCULAR CONCEPTS INC) 3 September 1997 (1997-09-03) column 7, line 22 -column 8, line 11 column 9, line 19 -column 10, line 6 column 10, line 43 -column 11, line 35 ---</p> <p>WO 00 45743 A (IMPRA INC) 10 August 2000 (2000-08-10) figures 1-3 claims 1-48 page 4, line 10 - line 14 page 5, line 2 -page 6, line 25 ---</p> <p style="text-align: right;">-/--</p>	1,8,15, 19,20
E		1,3,7,8, 10,14-20

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

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PCT/US 00/17448

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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